REMARKS

Following amendment herein, Claims 28–41 and 43–59 are pending in the application, of which Claims 38–40 and 45–59 are presently withdrawn from consideration as relating to groups other than the presently elected group. See Section 1 of the Response below for explanation why this list of withdrawn claims differs from that set forth in the present Action.

Independent Claim 28 is amended without prejudice herein to recite that where the drug is rotigotine (as opposed to a prodrug of rotigotine), it is in form of a base. This recitation is found in Claim 37 as originally filed, and is supported in the specification as filed, for example at p. 15, lines 17–18 of the English-language translation. Where rotigotine is recited in dependent claims, such claims are amended herein to recite the base form.

Following amendment of Claim 28 herein, Claims 37 and 42 are no longer differentiated. Accordingly, Claim 42 is canceled by the present amendment.

Opportunity is taken to correct errors and ambiguities of punctuation and grammar, and to present Markush groups in more standard form. The word "rotigotine" is corrected to replace an initial upper-case with a lower-case "r" to clarify that rotigotine is a generic name for the drug in question and is not a trademark.

No new matter is introduced and no change in inventorship is believed to result from the present amendment.

RESPONSE TO OFFICE ACTION DATED MAY 28, 2008

1. Election/restrictions

Applicant's traverse of the restriction requirement between Groups I and II is not accepted by the Examiner and the requirement has been made final (Action, p. 2). Applicant holds to the position that examination of Groups I and II, which differ only in that the system of Group II further comprises an internal-phase component, does not impose a greater search burden than Group I alone. For this reason, Applicant respectfully requests that at least the claims of Group II (Claims 38–40) be considered for rejoinder upon allowance of claims of Group I, to the extent that they incorporate all limitations of a base claim of Group I.

The Examiner's attention is respectfully drawn to an error in the present Action, by which Claims 41, 43 and 44 are withdrawn pursuant to 37 C.F.R. §1.142(b) as allegedly drawn to non-elected inventions.

Claim 41, originally placed by the Examiner in Group II, does not recite "an internal-phase component" and should have been placed in Group I. Claims 43 and 44, correctly placed by the Examiner in Group I according to the restriction requirement of February 7, 2008, are inexplicably withdrawn by the present Action.

Applicant accordingly requests reinstatement of Claims 41, 43 and 44. Following such reinstatement, the following claims should be subject to further examination: Claims 28–37, 41, 43 and 44.

2. Rejection under 35 U.S.C. §103(a) over Ulman in view of Müller

Claims 28–32, 34–37 and 42 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,658,975 ("Ulman") in view of U.S. Patent No. 6,620,429 ("Müller"). This rejection is moot for now-canceled Claim 42 and is respectfully traversed for remaining claims.

Independent Claim 28 is not obvious over Ulman in view of Müller at least for the reason that there is no apparent reason for a person of ordinary skill to select and combine features of the Ulman and Müller documents to approximate the claim, as required by *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007) (obviousness includes determining whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue). In particular, a person of ordinary skill would not look to combine a lipophilic drug (*e.g.*, rotigotine in base form) with a hot-melt adhesive expressly designed for improved performance with hydrophilic drugs. The Ulman and Müller teachings actually run counter to a finding of obviousness, as a skilled artisan would be dissuaded from selecting and joining the incompatible features of these teachings. See *In re Grasselli*, 713 F.2d 731, 218 USPQ 769 (Fed. Cir. 1983) (improper to combine references where the references teach away from their combination).

Claim 28 is drawn to a transdermal therapeutic system that comprises a drug-containing adhesive matrix in which the drug is the base form of rotigotine or a prodrug of rotigotine. The adhesive matrix contains a hot-meltable adhesive component that can be a single adhesive, a mixture of different adhesives or a mixture of an adhesive and a softener. The adhesive matrix exhibits a dynamic viscosity of not more than 100 Pa.s at 160°C.

Rotigotine is a lipophilic or hydrophobic compound and the base form is especially so.

Its lipophilicity can be attenuated by decreasing the pH (resulting in formation of salt), but it generally exhibits high lipid solubility. See the European Public Assessment Report of the European Medicines Agency (EMEA, 2006) for Neupro® transdermal rotigotine (www.emea.europa.eu/humandocs/PDFs/EPAR/neupro/062606en6.pdf, copy attached hereto), particularly at p. 1 thereof. See also Jankovic & Tolosa (2006) Parkinson's Disease and Movement Disorders, 5th ed., Philadephia: Lippincott, pp. 121–122, copy attached hereto.

Ulman, in contrast, describes a hot-melt pressure sensitive adhesive that has improved hydrophilic characteristics to afford the use of higher dosages of hydrophilic drugs. Ulman, col. 1, lines 63–67. In fact, it is an express object of Ulman "to provide a hot-melt silicon pressure sensitive adhesive composition that has improved hydrophilic characteristics while maintaining the pressure sensitive adhesive properties of shear, adhesion, and release." Ulman, col. 2, lines 3–7, 14–17. Ulman's adhesive is said to overcome earlier "hot-melt compositions [that] have been found to be inadequate for the delivery of hydrophilic drugs from transdermal drug delivery systems." Ulman, col. 1, lines 61–63. In view of Ulman's disclosure, there is no apparent reason for a person of ordinary skill to select the Ulman adhesive or a variant thereof for use with a lipophilic drug such as rotigotine, especially the base form of rotigotine.

The Ulman adhesive further includes siloxylated polyether waxes which are said to improve the hydrophilic characteristics, thus allowing quicker delivery of drugs that are hydrophilic in nature. Ulman, col. 7, lines 37–41. This stands in stark contrast to at least some embodiments of the present invention, wherein addition of a softener such as a wax permits delayed or slow release of rotigotine from an adhesive matrix, in some configurations release that may span several days (see English-language specification, p. 10, lines 9–13).

To establish a *prima facie* case of obviousness, there must be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Obviousness does not require absolute predictability; however, at least some degree of predictability is required and evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (no case for obviousness where there is no reasonable expectation of successfully combining features). In this case, a person of ordinary skill would not reasonably expect to adapt the

Ulman adhesive, which is expressly tailored for hydrophilic drugs, for developing a transdermal delivery system using a lipophilic drug such as rotigotine in base form (found in Müller).

Accordingly, independent Claim 28 and Claims 29–32 and 34–37 dependent therefrom are not obvious over Ulman in view of Müller. Withdrawal of the present rejection is respectfully requested.

3. Rejection under 35 U.S.C. §103(a) over Ulman in view of Müller & Noel

Claims 28 and 33 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,658,975 ("Ulman") in view of U.S. Patent No. 6,620,429 ("Müller"), further in view of U.S. Patent No. RE 36,754 ("Noel"). This rejection is respectfully traversed.

Claims 28 and 33 are not obvious over Ulman in view of Müller and Noel at least for the reason that there is no apparent reason for a person of ordinary skill in the art to combine these references in order to approximate the present claims. As described in the preceding section, Ulman teaches an adhesive composition tailored for hydrophilic drugs whereas Müller discloses the lipophilic (*i.e.*, hydrophobic) drug rotigotine. There is no basis for a skilled artisan to combine features of these references to approximate the instant claims; moreover a skilled artisan would not have a reasonable expectation of success in doing so. Addition of the Noel document fails to cure these defects and the combination hence fails to establish a *prima facie* case of obviousness.

Noel is provided for teaching use of the waxes ozokerite and ceresine to decrease dynamic viscosity of a hot-melt pressure-sensitive adhesive at temperatures up to 200°C. Noel, abstract; col. 5, lines 1 and 12–14. However, a person of ordinary skill in the art would not in the first place add the hydrophobic drug rotigotine, particularly in base form, to the hot-melt pressure-sensitive adhesive composition of Ulman, which is tailored for hydrophilic drugs, with or without further addition of the wax disclosed by Noel. As described in the preceding section, the premise for combining the pressure-sensitive adhesive of Ulman with rotigotine is flawed – a skilled artisan would not seek to adapt an adhesive designed for hydrophilic drug delivery to use with the hydrophobic drug rotigotine, especially the base form of rotigotine, as these elements have antithetical properties. Moreover, a skilled artisan

would not have a reasonable expectation of success in making such a combination that would approximate Applicants' claims. The waxes disclosed in Noel do not reconcile the disparate teachings of Ulman and Müller, hence the combination cannot establish a case of obviousness.

Accordingly, Claim 28 and Claim 33 dependent therefrom are not obvious over Ulman in view of Müller and further in view of Noel. Withdrawal of the present rejection is respectfully requested.

4. Obviousness-type double patenting

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over Claims 1–23 of co-pending U.S. application Serial No. 10/630,633 ('633).

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over Claims 15–36 of copending U.S. application Serial No. 10/139,894 ('894).

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over Claim 12 of copending U.S. application Serial No. No. 10/140,096 ('096).

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over Claims 1–6 of copending U.S. application Serial No. 10/139,894 ('894).

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1–120 of copending U.S. application Serial No. 11/239,701 ('701).

Claims 28–37 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1–110 of copending U.S. application Serial No. 11/239,772 ('772).

These rejections are provisional because the allegedly conflicting claims have not yet been patented. It is further noted that even if the present claims do conflict, ongoing prosecution of the reference application may result in amendments that would obviate the present double patenting rejection. Applicant therefore provisionally responds by undertaking

either to argue to overcome each of the above grounds of rejection or to provide a terminal disclaimer (to the extent necessary) once the present claims have been found to be otherwise allowable and/or any of the reference applications issues as a patent.

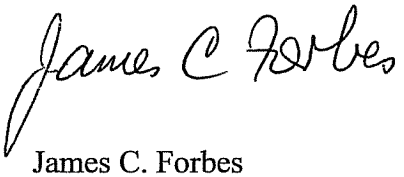
5. Conclusion

It is believed that all of the stated grounds of rejection are properly traversed, accommodated or rendered moot herein. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the present Action and that the application is in condition for allowance.

Should any issues remain, the Examiner is invited to call the undersigned at the telephone number given below.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.



James C. Forbes
Agent for Applicant
Reg. No. 39,457
Tel. 847-412-6350

Attachments:

EMEA (2006) European Public Assessment Report for Neupro®, pp. 1–40.

Jankovic & Tolosa (2006) Parkinson's Disease and Movement Disorders, 5th ed., Philadephia: Lippincott, pp. 121–122.